SACRAMENTO MEDICAL FOUNDATION | Blood Centers

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June 27, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Re: Guidance for Industry, Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens

Dear Sir:

I am in receipt of your recent Guidance Document entitled "Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens." I understand that a Final Rule, published on January 26, 1998, required that donor specimens be tested and found negative for certain infectious diseases, especially the AIDS virus, HIV 1, and HIV 2, plus Hepatitis B Virus and Hepatitis C Virus, using FDA-licensed donor screening tests as per the manufacturer's instruction. What is not clear is why "FDA-licensed screening tests labeled for cadaveric specimens must be used when available". Is there evidence that false-negative results will be obtained on cadaveric specimens when licensed assays for blood donor screening are used on specimens from deceased donors? If anything, samples, which are hemolyzed or lipemic, may give false-positive results, not false-negative ones.

The Guidance Document points out that there are now (only) two tests from one company which are licensed for use on cadaveric specimens, enabling testing for just HIV and HBV. However, there are no licensed tests for cadaveric specimens for testing for anti-HCV. Thus, it seems inconsistent to require tests licensed for cadaveric specimens for HIV and HBV while none are available for HCV, so we will, and can, continue to use tests licensed for blood donor screening for the latter. By requiring that only tests licensed and approved for cadaveric specimens be used, this would restrict users to the tests of one manufacturer, Genetics Systems. Since we use other licensed FDA tests at this time for testing of blood donors, as well as for testing of specimens from cadavers who are donors of organs and tissues, this would requires us to set up two technologies. Further, from our experience in evaluating many manufacturers' tests, while those of Genetics Systems meet the criteria for sensitivity, they generally are inferior to others for specificity. The additional false-positives from the use of Genetics Systems tests will further deplete the already insufficient number of available organs for transplantation.

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The timeframe for implementation of tests which have been licensed for cadaveric samples, of no later than January 31, 2001, is insufficient. Additional time should be provided for other manufacturers to qualify their tests on cadaveric samples and/or to permit collection of data to show the equivalency for an "alternative approach" using tests which are licensed for blood donor specimens.

Thank you for your consideration of the above comments.

Sincerely,

Paul Holland

Paul V. Holland, M.D.
Medical Director and Chief Executive Officer

Pc: Erica Bonney
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Return Service Requested

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